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Award Number: W81XWH-04-1-0487

TITLE: The Development of a Comprehensive Instrument to Measure Symptoms and Symptom Distress in Women After Treatment for Breast Cancer

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REPORT DATE: May 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	May 2005	Annual (16 Apr 2004 - 15 Apr 2005)

4. TITLE AND SUBTITLE
The Development of a Comprehensive Instrument to Measure Symptoms and Symptom Distress in Women After Treatment for Breast Cancer

5. FUNDING NUMBERS
W81XWH-04-1-0487

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

As women attempt to integrate the diagnosis of breast cancer into their lives, dealing with residual symptoms and symptom distress after treatment is complete can affect functioning and the quality of life. Little is known about the actual symptom experience, symptom distress, and symptom trajectory after adjuvant treatment is complete. There are three aims of this study: (1.) Identify the full scope of symptoms and symptom distress in women with breast cancer after adjuvant treatment; (2.) develop a comprehensive instrument to measure symptoms and symptom distress after treatment; (3.) test the new instrument using future funding. The initial component of this award consisted of the Principal Investigator taking formal courses in scientific oncology, women's issues, and instrument development, all of which have been completed. The next component dealt with subject recruitment, interviewing, and questionnaire completion. To date, 41 out of 100 women have been recruited. The most common symptoms are: insomnia, fatigue, poor concentration, and diminished outlook; the most distressful are: menopausal symptoms, muscle and joint pains, and peripheral neuropathies and affect functioning, quality of life, and last well into a year after treatment. Though concerned about future wellness, most women found their healthcare providers and family supportive.

14. SUBJECT TERMS
Breast cancer, symptoms/symptom distress, instrument development

15. NUMBER OF PAGES
10

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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Introduction

As women attempt to integrate the diagnosis of breast cancer into their lives, functioning and quality of life issues arise. It has been postulated that weight gain, menopausal symptoms, and sexuality become prominent sources of symptom distress in the months and years after adjuvant therapy (Knobf, 2000), but little is known about the actual symptom experience, symptom distress and symptom trajectory after adjuvant treatment is complete. Furthermore, there are no comprehensive instruments to measure symptom distress in women with breast cancer during this time period.

The specific aims of this study are to: identify the full scope of symptoms and symptom distress in women with breast cancer after adjuvant treatment, develop a comprehensive instrument to measure symptoms and symptom distress in women with breast cancer after adjuvant treatment, and eventually test this new instrument. The study is guided by the UCSF Symptom Management Conceptual Model. Data from 100 women (50 one to six months after therapy; 50 six to twelve months after therapy) will be obtained using a battery of instruments measuring uncertainty (Mishel Uncertainty in Illness Scale), menopausal symptoms (Breast Cancer Prevention Trial Checklist), symptom distress (McCorkle Symptom Distress Scale, Symptom Checklist-90-Revised), and functioning (Functional Assessment of Cancer Therapy-Breast). Descriptive statistics will analyze demographic and medical information. Rank/ordering will identify the most prominent and persistent symptoms causing women distress. These symptoms will then be incorporated in a new and comprehensive tool to measure symptom distress.

Body

The first aim of this study was to identify the full scope of symptoms and symptom distress in women with breast cancer after adjuvant treatment.

<u>Spring 2004:</u>

- Course: Oncology for Scientists I taken at Roswell Park Cancer Institute: Gain an understanding of cancer pathology and symptomatology. The course consisted of information on malignant transformation, growth and spread of cancer, genetic mutation, epidemiology. This knowledge provided an in depth understanding of the cancer process and the resultant cancer treatments and symptoms encountered. Information from this course also provided insight into individual susceptibility to develop cancer both from a compromised immune system, epidemiology, or genetic predisposition.
- I worked closely with Dr. Joyce Yasko, the Director of Research Protocols at Roswell Park. Here I became acquainted with the practical application of three types of studies: pharmacologic, investigative, and cooperative. The role of the research nurses, their training, as well as monitoring studies for adherence to protocols was a great part of this experience. I attended the Scientific Review Committee where I learned how research protocols are reviewed for patient risk as well as plans to deal with adverse outcomes. This insight will be helpful as I prepare future research studies. Meeting with the budget chair at Roswell provided insight on how to prepare a research proposal and budget in concert. As a new researcher, I give great attention to the development of research protocols while giving budgetary requirements less attention. Working with Dr. Yasko I learned that research protocols and the budget should be done in concert. Observing budgetary meetings provided additional information on the

feasibility of performing studies and staying on target as to costs.

- Course: Psycho-Social Measurement and Questionnaire Construction taken in the School of Nursing at the University at Buffalo. This course focused on psychometric theory and its application in health and behavioral sciences. Content included scaling methods, in depth evaluation of the reliability and validity of an instrument, factor analysis, and construction of survey questionnaires and attitudinal rating scales. This information will be invaluable as I develop my new comprehensive instrument to measure symptoms and symptom distress in women with breast cancer after treatment completion.
- Worked on the required Department of Defense written protocol. Permission was sought and received from the University at Buffalo Health Sciences Internal Review Board to proceed with the study. Permission was sought and received to use the battery of instruments in this study.

<u>Fall 2004:</u>

- Course: Oncology for Scientists II at Roswell Park Cancer Institute. This course was a sequel to the course in the Spring of 2004 and focused on biostatistics and organ-specific cancers. It provided information about specific cancers, their diagnosis, treatment and prognosis.
- Subject recruitment was delayed until late Fall 2004 because the written protocol was not approved by the Department of Defense until late August with actual letter approving the protocol not received until late October. Subject recruitment was started November 1st 2004. To date 41 women (23 in group one and 18 in group two) have been recruited and have completed the questionnaires. Preliminary data analysis using descriptive statistics shows the following findings:
  - McCorkle Symptom Distress Scale-> the most distressing symptoms are insomnia, fatigue, diminished concentration, and diminished outlook.
  - Mishel Uncertainty in Illness Scale-> most frequent concern centers on future change in health status. Women felt well informed by their physicians, they could depend on them, and they were given information in clear, understandable terms.
  - Breast Cancer Prevention Trial Checklist-> most frequent and distressing symptoms were joint pain, muscle stiffness, weight gain, forgetfulness, problems with appearance, numbness and tingling, night sweats, and early awakenings. It should be mentioned that all the women to date like this questionnaire and felt with a few exceptions it captured their symptoms and distress the most accurately.
  - Functional Assessment of Cancer Therapy – Breast-> two concerns were clear: they experienced a lack of energy and were worried about family members getting the disease. Most women reported support from family and friends and that they were able to carry on with their lives.
  - Symptom Checklist-90-Revised-> sore muscles, trouble sleeping, low energy, and problems remembering were the chief symptoms identified as distressful. Most women did not like this questionnaire as there are many psychological/psychiatric questions and the majority of women felt strongly that they were not applicable.

  The CARES tools was eliminated from this study after consultation with Drs. Brown, McCorkle, and Knobf, as it was long and included all the same constructs in the other five questionnaires.

Spring 2005:

- Continue subject recruitment, data entry, and data analysis.
- Work with Dr. Knobf and a gynecologist/endocrinologist to learn more about menopausal pathology and symptomatology.

Aim two was to develop a comprehensive instrument to measure symptoms and symptom distress in women with breast cancer after treatment completion.

- At this point in the study, the new instrument to be developed would use the BCPT questionnaire as a baseline tool, eliminate the symptoms women generally scored as zero and incorporate the above stated concerns and symptoms. Of particular interest is the fact that while some symptoms abate slightly in the second group (7 to 12 months after treatment), menopausal symptoms and neuropathies persist and really impact functioning and quality of life.
- Data entry and preliminary analyses have begun as described above. Based on these findings the new instrument will be comprised of between 20-25 items. Of interest is that when some questions are read and answered by the women, they voice a sense of relief that these symptoms occur, almost validating how they feel.

The third aim was to develop a grant proposal to support the psychometric testing of the new instrument.

Summer 2005

- To that end, instead of taking a grantsmanship course at the University at Buffalo, Dr. Jean Brown thought it would be more beneficial if I went to UNC-Chapel Hill School of Nursing and took part in the Grant Writing Institute. The institute consists of five days of education and writing guided by Dr. Sandra Funk, a nationally known and funded nurse researcher. This week-long institute was designed so that participants will author a successful research grant for federal funding.

Once completed, federal funding will be sought from either NCI or NIH for instrument testing. I will test the instrument on women in the Buffalo area and Dr. Knobf has agreed to test it at Yale, New Haven Medical Center. This new instrument has the potential not only to be used to measure symptom distress in women after treatment completion, but also for women with breast cancer during treatment. The symptoms causing women concern and distress after treatment completion are the same symptoms experienced during treatment. No one instrument currently available consists of items women are experiencing. To validate their symptomatology and accurately measure their distress, this new instrument has the potential to accurately measure symptom distress in women with breast cancer. Once this can be accurately measured, appropriate interventions can be designed to reduce the distress.

I have been in close contact with my mentor Dr. Jean Brown as well as with Drs. McCorkle and Knobf. There have been no problems/concerns voiced from the women recruited for this study to date. Women are very anxious to tell of their experiences so that others might be helped.

Key Research Accomplishments

- The most prominent and distressing symptoms are: muscle & Joint pain, neuropathies, fatigue, and menopausal symptoms (hot flashes, night sweats, and sleeping disturbances.
- Women voiced concerns over "being alone after treatment" and frightened about the even the smallest changes in their health.

Reportable Outcomes

- Abstract of preliminary findings to be presented at the Era of Hope meeting in June 2005 in Philadelphia.
- Completed results to be submitted to the Oncology Nursing Congress as a podium presentation in Spring 2006.
- Manuscripts on results both residual symptoms women experience after treatment completion and on the newly developed instrument are planned on being submitted to both *Cancer Nursing* and *Oncology Nursing Forum.*

Conclusion

Women continue to experience side effects of treatment and symptoms well after the completion of adjuvant therapy. Muscle and joint pains, neuropathies, and menopausal symptoms persist in the year after treatment and truly affect their functioning and quality of life. Women also expressed feelings of aloneness and worry about their future. As health care providers we must be cognizant of these persistent symptoms and women's feelings and concerns once treatment is over. Understanding their symptoms and resulting distress as well as keeping women connected with their health care provider could enhance their quality of life.

References

Knobf, M. Tish. (2000). Symptom distress before, during and after adjuvant breast cancer therapy. *Developments in Supportive Cancer Care, 4*(1), 13-17.

Title: The Development of a Comprehensive Instrument to Measure Symptoms and Symptom Distress in Women with Breast Cancer after Treatment Completion.

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Scientific Abstract

Significance: As women attempt to integrate the cancer diagnosis into their lives, functioning and quality of life issues arise. It has been postulated that weight gain, menopausal symptoms, and sexuality become prominent sources of symptom distress in the months and years after adjuvant therapy (Knobf, 2000), but little is known about the actual symptom experience, symptom distress and symptom trajectory after adjuvant treatment is complete. Furthermore, there are no comprehensive instruments to measure symptom distress in women with breast cancer during this time period. Breast cancer patients are the most frequent survivors, therefore it is critical that healthcare providers recognize the affect of both the breast cancer diagnosis and its treatment on the life of women after the acute treatment phase.

Specific Aims: (1) Identify the full scope of symptoms and symptom distress in women with breast cancer after adjuvant treatment; (2) Develop a comprehensive instrument to measure symptoms and symptom distress in women with breast cancer post adjuvant treatment.

Study Design: The proposed cross-sectional, correlational study will be guided by the UCSF Symptom Management Conceptual Model. Data from 100 women (50 one to six months after therapy; 50 six to twelve months after therapy) will be obtained using a battery of instruments measuring uncertainty (Mishel Uncertainty in Illness Scale), menopausal symptoms (Breast Cancer Prevention Trial Checklist), symptom distress (McCorkle Symptom Distress Scale, Symptom Checklist-90-Revised), and functioning (Functional Assessment of Cancer Therapy-Breast). Descriptive statistics will analyze demographic and medical information. Rank/ordering will identify the most prominent and persistent symptoms causing women distress. These symptoms will then be incorporated in a new and comprehensive tool to measure symptom distress.

Findings: To date (11/04) data has been collected on 15 women (5 from 0 to 6 months and 10 from 7 to 12 months) after treatment completion. The most distressing symptoms are: muscle & joint pain, neuropathies, fatigue, and menopausal symptoms (hot flashes, night sweats, and sleeping disturbances). Women frequently voiced concerns of "being alone" now that treatment is over and frightened about the smallest change in their health. Symptoms persist over the course of one year with 10 women in the 7 to 12 month category still reporting residual, bothersome symptoms.

Implications: As women enter the breast cancer survivor realm after treatment completion, they continue to experience physical symptoms and emotional concerns. Life long consequences of breast cancer treatment must be recognized, addressed, and managed by healthcare providers if survivors are to enjoy the lives they will go on to live. Young women, who suddenly feel older because of chemically induced menopause, have the potential to develop serious problems.